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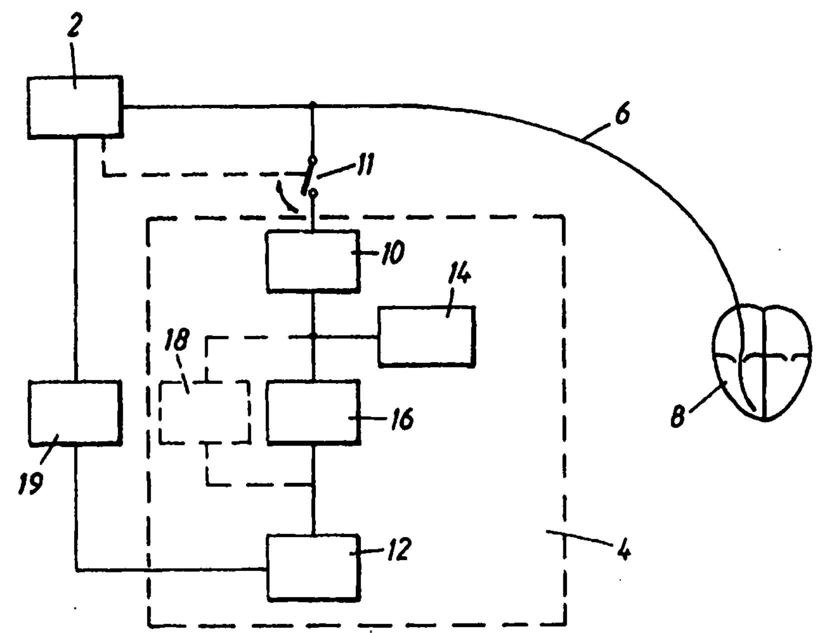
(57) Abstract



An evoked response detector for a heart stimulator determines evoked response in the presence of polarization. To determine the magnitude of the polarization for different stimulation amplitudes, the electrode signals picked up by the lead after the delivery of one high and one low amplitude stimulation pulse are measured. The low amplitude stimulation pulse has amplitude equal to known stimulation threshold plus a predetermined voltage step. Calculating means determine the difference between the electrode signals picked up and forms the quotient between said difference and the difference between the high and low stimulation pulses amplitudes. Analysing means determine the evoked response signal by subtracting from electrode signals subsequently picked up, polarisation signals of a magnitude equal to the actual stimulation pulse amplitudes, multiplied with said quotient. Alternatively, the generator delivers a stimulation pulse of a high amplitude and then stimulation pulses of amplitudes successively lowered by a predetermined voltage step to a low stimulation amplitude equal to the known stimulation threshold plus one of said voltage steps. Calculating means determine and store the magnitude of the polarisation per voltage step, Pol_{step}. Analyzing means determine evoked response signals by subtracting from electrode signals subsequently picked up a polarisation signal of a magnitude equal to the quotient between the actual stimulation amplitude and said voltage step and multiplied by the stored Pol_{step}.

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EVOKED RESPONSE DETECTOR FOR A HEART STIMULATOR

Technical Field

The present invention relates to an evoked response detector for a heart stimulator for determining evoked response in the presence of polarisation, said heart stimulator comprising a pulse generator and control means for controlling said pulse generator to produce stimulation pulses of varying amplitudes, and a lead being intended to be introduced into the heart of a patient and connected to the pulse generator for delivering stimulation pulses to the heart, said evoked response detector comprising measuring and memory means for measuring and storing the electrode signal picked up by the lead in response to delivered stimulation pulses.

Background Art

To reduce the energy consumption of heart stimulators an automatic threshold search function, a so called AUTOCAPTURE™ function, is provided to maintain the energy of the stimulation pulses at a level just above that which is needed to effectuate capture, cf. e.g. US-A-5,458,623. A reliable detection of the evoked response, which then is necessary, is, however, not a simple matter, especially when it is desired to sense the evoked response with the same electrode as the one delivering the stimulation pulse. The reason therefore resides in the fact that the evoked response potential is small in amplitude compared to the residual polarization charge. The residual charge decays exponentially but tends to dominate the evoked potential for several hundreds of milliseconds after the stimulation. If the polarization is too high, it could be wrongly interpreted by the evoked response detector as a capture, i.e. contraction of the heart. The AUTOCAPTURE™ algorithm could then by mistake adjust the output amplitude of the stimulation pulse to a value below the actual capture level, which will result in no capture. If the used pacing lead has significant

polarization this could consequently disturb the AUTOCAPTURE™ function and result in loss of capture.

Several attempts have been made to solve the lead polarization problems in connection with evoked response detection. One way of reducing these problems is to use special low polarizing leads.

Another method is described in US-A-5,417,718, which discloses a system for maintaining capture wherein electrical post-stimulus signal of the heart, following delivery of a stimulation pulse, is compared to a polarization template, determined during a capture verification test. A prescribed difference between the polarization template and the post-stimulus signal indicates capture. Otherwise loss of capture is presumed and the stimulation energy is increased a predetermined amount to obtain capture.

In US-A-5,697,957 a method and an apparatus are descsribed for extracting an evoked response component from a sensed cardiac signal by suppressing electrode polarization components. An autocorrelation function is then calculated according to an autocorrelation algorithm and applied to the sensed cardiac signal. The autocorrelated signal thus obtained and the sensed cardiac signal are normalized and the difference between these two normalized signals is formed to thereby extract the evoked response component if it is present.

There is mostly at least one significant slope in the bipolar measured IEGM signal, which makes it possible to discriminate the evoked response signal from slowly varying signals such as polarization signals. Thus in US-A-5,431,693 a method of verifying capture of the heart by a cardiac pacemaker is described. Observing that the non-capture potential is exponential in form and the evoked capture potential, while generally exponential in form, has one or more small-amplitude perturbations superimposed on the exponential wave form, these perturbations are enhanced for ease of detection

by processing the wave form signal by differentiation to form the second derivative of the evoked response signal for analysis for the evoked response detection.

Unipolar detection of evoked response signals is however not possible by this technique. Abrupt slope changes or superimposed small-amplitude perturbations are leveled out if the measurements are made over the longer distance from the electrode to the stimulator casing.

The unipolar sensed evoked response signal thus differs from the bipolar sensed evoked response signal both in duration and amplitude, see Baig et al, "Comparison of Unipolar and Bipolar Ventricular Based Evoked Responses", Br Heart J. 1992, 68: 398-402. The duration of the evoked QRS complex is a measure of total ventricular bipolarization time in the area of the heart subtended by a sensing bipole, and it depends on the extension of the bipole. This means that the unipolar evoked response signal measured between the electrode tip and the casing of the heart stimulator has a longer duration than the bipolar evoked response measured between tip and ring electrodes. This is illustrated in figure 1 in which the upper curve shows an unfiltered cardiac signal measured by a unipolar lead and the lower curve the cardiac signal sensed by a bipolar electrode. Previously known evoked response detectors, the function of which is based on the detection of a slope of the evoked response signal, typical in a detection window of 15-60 msesc after the stimulation pulse, are therefore not suited for detection of evoked response by unipolar electrodes.

It has now appeared that the evoked response signal amplitude is fairly constant, independent of the stimulation pulse amplitude, i.e. the evoked response signal amplitude does not vary with the amplitude of the stimulation pulse (provided that the stimulation amplitude is above the capture threshold). Further, it has been found that the electrode polarization is approximately linearly dependent on the

stimulation pulse amplitude for a constant pulse duration, cf. Swedish patent application No. 9703600-8.

The purpose of the present invention is to provide a new detector for determining evoked response based on the above circumstances and is not depending on any slope measurements on the sensed signal, which detector can be used with both low- and highpolarizing unipolar sensing electrode leads.

Disclosure of the Invention

This purpose is obtained with an evoked response detector according to the introductory portion of the description having the characterizing features of claim 1.

Thus in the detector according to the invention the polarization arising after a stimulation pulse which is a problem for safe detection of evoked response, is reduced to such an extent that also unipolar detection can be performed reliably. This is an important advantage since unipolar leads are less complicated to manufacture and have longer working life than bipolar electrodes. The detector according to the invention also makes it possible to determine in a reliable way when the AUTOCAPTURE™ function of a heart stimulator can be activated. Thus the use of such heart stimulators can be extended also to patients having unipolar leads. Another advantage of the detector according to the invention is that no extra stimulation pulses, resulting in extra current draining, are needed as in previously known techniques for measuring the polarization.

According to advantageous embodiments of the detector according to the invention the pulse generator is controlled to deliver at least one high amplitude stimulation pulse and one low amplitude stimulation pulse a plurality of times, and in that said measuring and memory means are adapted to measure the corresponding electrode signals picked up by said lead after each stimulation pulse for calculating a corresponding plurality of said quotient, said calculating

means forming an average quotient value of said plurality of quotients to be used for subsequent determination of the evoked response. The pulse generator can also be controlled to deliver a plurality of series of stimulation pulses, each series starting with a high stimulation amplitude pulse and ending with a low stimulation amplitude pulse, and the calculating means is adapted to determine the magnitude of the polarization per voltage step Pol_{step} from electrode signals picked up from each series of pulses and forming an average value of the obtained plurality of polarization per voltage step Pol_{step}, said average value being stored for use as said stored polarization per voltage step Pol_{step} for subsequent determination of the evoked response signal. For determining the evoked response signal said measuring and memory means can further be adapted to sample the electrode signal picked up by the lead with a predetermined sampling frequency during a predetermined time interval after the delivery of a stimulation pulse for calculating a mean value of these sampled values. By these determinations of mean or average values small variations and interferences in the measured evoked response and polarization signals are suppressed.

According to still other advantageous embodiments of the detector according to the invention said measuring and memory means are adapted to measure the electrode signal picked up by the lead before the delivery of a stimulation pulse to determine a DC level to be subtracted from the electrode signal picked up after the delivery of a stimulation pulse. The measuring and memory means can be adapted to measure the electrode signals picked up by the lead before the delivery of each stimulation pulse of the high amplitude and the low amplitude respectively and said calculation means can be arranged to determine the average value of these measured signals prior to the stimulation pulse as the DC level to be subtracted from measurement signals picked up after the delivery of stimulation pulses. By subtracting the DC level

from the measured electrode signal in this way the real magnitude of this signal is obtained.

According to other advantageous embodiments of the detector according to the invention comparison means are provided for comparing said determined evoked response signal with a predetermined limit to determine whether capture is present or not. The pulse generator can be controlled to deliver a plurality of stimulation pulses of high stimulation amplitude and a plurality of low amplitude stimulation pulses and said calculating means can be adapted to form an average value of the plurality of evoked response signals resulting from the stimulation pulses of high amplitude and an average value of the plurality of evoked response signals resulting from the low amplitude stimulation pulses, said average values being supplied to said comparison means for comparison with said predetermined limit value. In this way it is possible to detemine not only whether capture is present or not, but also if the AUTOCAPTURE™ function of the heart stimulator can be activated or not.

Brief Description of the Drawings

To explain the invention more in detail embodiments of the detector according to the invention chosen as examples will now be described with reference to the drawings, on which

figure 1 shows the unfiltered electrode signal picked up by a unipolar lead and a bipolar lead respectively,

figure 2 shows the measured electrode signal for four different stimulation pulse amplitudes and the evoked response signals with the polarization signals subtracted respectively,

figure 3 is a block diagram of the principal layout of the detector according to the invention, and

figure 4 is a block diagram of an embodiment of the evoked response detector according to the invention.

Description of Preferred Embodiments

The polarization of a pacemaker electrode can be described as

$$Pol = \frac{U_{stim}}{\alpha} * f(dur; RC_{output})$$

where Pol designates the polarization signal, U_{stim} the pacemaker stimulation pulse amplitude, α is a constant, dur designates the duration of the stimulation pulse and RC_{output} is the time constant of the pacemaker output lead system, see Konrad Mund, "Analysis of the polarization and the sensing behavior of electrodes for cardiac pacemakers", Pacemaker leads, Elsevier Science Publishers BV, 1991.

Thus, according to the equation above the polarization is a function of the duration dur of the stimulation pulse and the time constant RC_{output}. This means that if the duration dur of the stimulation pulse and the time constant RC_{output} are constant for different stimulation pulse amplitudes the polarization Pol is only depending on the stimulation pulse amplitude U_{stim} and this dependency is linear.

Studies on animals show that the evoked response signal amplitude ER is fairly constant for different stimulation pulse amplitudes U_{stim} and independent of the stimulation pulse duration dur. This is illustrated in fig. 2, which shows the electrode signal (IEGM) for different stimulation amplitudes as a function of time. Thus the electrode signals are recorded from immediately after the stimulation complex is delivered, time 0, and until approximately 70 msec after the stimulation. Curve A is obtained for a stimulation pulse amplitude of 0.6 V, curve B is obtained for a stimulation pulse amplitude of 1.5 V, curve C is obtained for a stimulation pulse amplitude of 3.0 V, and curve D for a stimulation pulse amplitude of 4.5 V.

Each curve represents the sum of the evoked response signal and the polarization signal. As the evoked response signal is essentially constant it is apparent from the figure that the polarization signal varies significantly with the used stimulation pulse amplitude.

At the top of the figure the evoked response signals with the polarization subtracted are shown.

Fig. 3 shows a block diagram of the principal layout of the detector according to the invention incorporated in a heart stimulator. The stimulator comprises a pulse generator 2 which through a lead 6 is connected to the heart 8 of a patient. The pulse generator 2 is controlled by controlling means 19 to produce stimulation pulses of varying amplitudes which through the lead 6 are transferred to the heart 8. The evoked response detector 4 is also connected to the lead 6. The evoked response detector 4 comprises a filter, measuring and memory means 10 and the filtered electrode signal is supplied to calculating means 16 and to analyzing means 12 for determining the polarization and the true evoked response signal.

The means 10 is disconnected by the switch 11 from the lead 6 during stimulation. As a consequence the electrode signal obtained before the stimulation in question will be stored in the means 10. When the evoked response detector is enabled after a stimulation the difference between the electrode signal before stimulation and after is supplied to the calculation and analyzing means 12, 16.

Timing means 14 are provided for determining an evoked response window during which the electrode signal is measured and stored. This evoked response window normally extends from 15 to 55 msec after stimulation.

As an alternative an averaging means 18 can be provided for forming the average value of a predetermined number of measured electrode signals.

Fig. 4 shows in more detail one embodiment of the evoked response detector according to the invention. The heart electrode signal picked up by the lead 6 in fig. 3 is then supplied to a highpass filter 20. An amplifier 22 and an A/D converter 24 are provided for amplifying and A/D converting respectively the filtered signal. The block 26 comprises a

digital signal processor for calculating the polarization as will be described more in detail below and determining the true evoked response signal.

Thus in the embodiment shown in fig. 4 the algorithm for determining whether an evoked response is detected or not is implemented in software by use of a microprocessor. Instead of a microprocessor this algorithm can also be implemented in random logic, which means realization by ordinary logic element, that is logic gates.

The detector according to the invention can also be implemented in the heart stimulator electronics by use of switch capacitor (SC) technique. The algorithm is then implemented in SC technique, where different capacitors serve as memory elements for storing the different electrode potentials and SC-adding, subtracting and multiplying circuits are used for performing the necessary calculations as explained above.

In the detector according to the invention the polarization is calculated for determining the true evoked response signal for determining whether capture is obtained or not, and possibly for activating an AUTOCAPTURE™ function of the heart stimulator in question. A requirement is then that the stimulation threshold value is previously known, and this threshold value can be determined by the technique according to the co-pending Swedish patent application No.: .. (our ref.: 98P2015SE).

To be able to decide whether the AUTOCAPTURE™ function can be activated or not the polarization signal for the lowest stimulation amplitude, e.g. 0,3 V, is determined. In this example it is assumed that the amplitude resolution is 0.3 V. The mean value of the amplitude of the evoked response signal (with the polarization signal subtracted), is calculated for a low stimulation amplitude, e.g. 0,6 V, and a high stimulation amplitude, e.g. 4.5 V. The duration of the

stimulation pulses is supposed to be equal to the pulse duration when determining the stimulation threshold value.

If the stimulation threshold value is less than a predetermined value X, e.g. ≅2 V, the detector illustrated in figures 3 and 4, operates as follows.

The unipolar IEGM measured between the electrode tip of the implanted ventricular lead 6 and the pacemaker casing is filtered by an analog bandpass filter with a cut-off frequency of 1 Hz to 130 Hz. Before the emission of a stimulation pulse, with a unipolar or bipolar electrode configuration, the IEGM signal is sampled. The mean value of these samples is calculated and represents the DC level. The stimulation pulse followed by the fast discharge pulse is then delivered.

The evoked response detector is blanked a predetermined time from the beginning of the stimulation pulse, for example during 15 msec. When the blanking time is terminated the picked up IEGM signal is sampled and digitized. The sampling frequency can be e.g. 512 Hz and the sampling occurs for a predetermined time interval called the evoked response window. The DC level is subtracted from each sample.

To remove the polarization, a certain amount of polarization, achieved from a polarization algorithm described below, is subtracted from the measured electrode signal (IEGM). The number of polarization steps Pol_{step} equals the stimulation amplitude divided by the voltage step which the heart stimulator in question uses between consecutive stimulation amplitudes. For example, if the stimulation amplitude is 4.5 V and the voltage step is 0.3 V, 15 Pol_{step} signals will be subtracted. Thereafter the mean value of all samples, after subtractions, is calculated, and this mean value represents the mean amplitude of the evoked response signal.

As mentioned above the detector according to the invention is based on the fact that the true evoked response signal is independent of the stimulation amplitude, and this true

evoked response signal ER equals the signal sampled during the evoked response window with the polarization signal subtracted. Thus, the difference in the measured electrode signal in the evoked response window is mainly due to the polarization. The detector subtracts the polarization signal resulting for the stimulation amplitude in question before it decides whether capture has occurred or not. The polarization signal is determined with the algorithm below.

The so called Vario cycle is started as usual, i.e.

1. Simulation starts at the highest amplitude, e.g. 4.5 V, and is continued in voltage steps down to the lowest amplitude, which is equal to the stimulation threshold amplitude at the pulse width chosen plus one voltage step.

2. A predetermined number of samples are taken before the highest and lowest stimulation pulse in the Vario cycle and the average value is calculated to get the DC level.

3. The measured electrode signal (IEGM) is sampled during the evoked response window following the highest and lowest stimulation pulses.

4. The DC level is subtracted from both the measured electrode signals to get the real amplitudes of these signals.

5. The achieved signals for the lowest stimulation amplitude is then subtracted from the achieved signal from the highest stimulation amplitude.

6. The resulting signal will be divided by the number of voltage steps between the highest stimulation amplitude and the lowest stimulation amplitude to get the Pol_{step} signal. For instance, if the highest amplitude is 4.5 V, the lowest stimulation amplitude is 0.9 and the step is 0.3 V, the resulting signal will be divided by

$$\frac{4.5 - 0.9}{0.3} = 12.$$

The steps 1-6 above are repeated a predetermined number of times and the average value of Pol_{step} is calculated. This value is then stored and used to eliminate the polarization from the measured electrode signal for each subsequent heart beat when the detector is working.

If the stimulation threshold value > X the polarization step Pol_{step} is determined by stimulating a predetermined number of times with pulses of an amplitude equal to the threshold value minus 0.3 V. In this case capture is, of course, not obtained and the mean value of the measured electrode signals is stored as $Pol_{thres-0.3}$.

The polarization for a stimulation pulse of 0.3 V is then calculated as

$$Pol_{0.3} = \frac{Pol_{thresh-0.3}}{K}$$

where $K = \dfrac{U_{stimthresh-0.3}}{0.3}$

The quantity Pol_{step} can be calculated in different ways, and the above described methods are just examples of such calculations, but it is important that the stimulation amplitude is changed in comparatively small steps in order to get correct DC levels.

When using just a high stimulation amplitude and a low stimulation amplitude for determining the Pol_{step} there should be a big step between these two amplitudes but by stimulating several times at both the high and the low amplitude before the sampling takes place, there will be no big step before the signals used in the calculations of the Pol_{step}. Incorrect DC levels will, of course, give false Pol_{step} signals.

When the Pol_{step} signal is calculated an evoked response sensitivity test can be performed to determine e.g. if an AUTOCAPTURE™ function can be activated. This test is performed on the true evoked response signal, that is the measured signal with the polarization signal subtracted. If the absolute amplitude of the true evoked response signal is

larger than a predetermined value an evoked response threshold level can be set and the AUTOCAPTURE™ function be activated.

An example of how such an evoked response sensitivity test can be performed is as follows:

1. A predetermined number of stimulation pulses of high amplitude, preferably the highest available amplitude, e.g. 4.5 V is emitted, and the measured electrode signals are sampled in the evoked response window. The DC level and the corresponding number of Pol_{step} signals are subtracted. Thus, if the stimulation amplitude is 4.5 V and the voltage step is 0.3 V the number of Pol_{step} will be 15. Then stimulation is performed with low amplitude, preferably the lowest stimulation amplitude, and the DC level and corresponding number of Pol_{step} are subtracted. The number of Pol_{step} will be equal to the low stimulation amplitude divided by the voltage step.

2. The average amplitude of the resulting signal $ER_{highamp}$ for the high stimulation amplitude pulses is calculated.

3. The average amplitude of the resulting signal ER_{lowamp} for the low stimulation amplitude pulses is calculated.

4. If max ($ER_{highamp}$, ER_{lowamp}) < a predetermined value AUTOCAPTURE™ can be activated and evoked response threshold value be set according to predetermined rules.

Evoked response signal amplitudes below this threshold value will then be considered as capture, and evoked response signal amplitudes above this threshold level as loss of capture, i.e. a backup pulse of higher amplitude will be emitted. It should be noted that the signals in question are negative.

If the stimulation threshold value > X ER_{lowamp}, e.g. $ER_{0.6}$, must be calculated as follows if the threshold value exceeds 0.3 V.

$ER_{0.6} = ER_{4.5} - 13 \times Pol_{0.3}$ (=Pol_{step}). If the stimulation

threshold value equals 0.3 V $ER_{0.6} = ER_{thresh+0.3}$. In this case $ER_{0.6} = ER_{lowamp}$.

CLAIMS

1. An evoked response detector for a heart stimulator for determining evoked response in the presence of polarization, said heart stimulator comprising a pulse generator (2) and control means for controlling said pulse generator to produce stimulation pulses of varying amplitudes, and a lead (6) being intended to be introduced into the heart (8) of a patient and connected to the pulse generator for delivering stimulation pulses to the heart, said evoked response detector (4) comprising measuring and memory means (10, 14) for measuring and storing the electrode signal picked up by the lead in response to delivered stimulation pulses, characterized in that in order to determine the magnitude of the polarization for different stimulation amplitudes, said measuring and memory means are measuring the electrode signal picked up by the lead (6) after the delivery of at least one high amplitude stimulation pulse and one low amplitude stimulation pulse, said low amplitude stimulation pulse having an amplitude equal to a known stimulation threshold voltage plus a predetermined voltage step, in that a calculating means (16) is provided to determine the difference between the electrode signals picked up after said high and low amplitude stimulation pulses and forming the quotient between said difference and the difference between said high and low stimulation amplitudes, and in that analyzing means (12) are provided to determine the evoked response signal by subtracting from electrode signals, subsequently picked up, polarization signals of a magnitude equal to the actual stimulation pulse amplitudes, multiplied by said quotient.

2. An evoked response detector for a heart stimulator for determining evoked response in the presence of polarization, said heart stimulator comprising a pulse generator (2) and control means for controlling said pulse generator to produce stimulation pulses of varying amplitudes, and a lead (6)

being intended to be introduced into the heart (8) of a patient and connected to the pulse generator for delivering stimulation pulses to the heart, said evoked response detector (4) comprising measuring and memory means (10, 14, 16, 18) for measuring and storing the electrode signal picked up by the lead in response to delivered stimulation pulses, c h a r a c t e r i z e d i n that in order to determine the magnitude of the polarization for different stimulation amplitudes, said control means is controlling the pulse generator to deliver a stimulation pulse of a high stimulation amplitude and then delivering stimulation pulses of amplitudes successively lowered by a predetermined voltage step to a low stimulation amplitude equal to the known stimulation threshold level plus one of said voltage steps, in that said measuring and memory means are measuring and storing said electrode signal after the delivery of the stimulation pulse of high amplitude, and of low amplitude respectively, in that a calculating means is provided to determine the difference between the electrode signal picked up after the delivery of the stimulation pulse of high amplitude and the electrode signal picked up after the stimulation pulse of low amplitude and dividing the obtained difference with the number of voltage steps therebetween to determine and store the magnitude of the polarization per voltage step Pol_{step}, and in that analyzing means are provided to determine evoked response signals by subtracting from electrode signals subsequently picked up a polarization signal of a magnitude equal to the quotient between the actual stimulation amplitude and said voltage step and multiplied by the stored polarization per voltage step Pol_{step}.

3. An evoked response detector for a heart stimulator for determining evoked response in the presence of polarization, said heart stimulator comprising a pulse generator (2) and control means (18) for controlling said pulse generator to produce stimulation pulses of varying amplitudes, and a lead (6) being intended to be introduced into the heart (8) of a

patient and connected to the pulse generator for delivering stimulation pulses to the heart, said evoked response detector (4) comprising measuring and memory means (10, 14,) for measuring and storing the electrode signal picked up by the lead in response to delivered stimulation pulses, c h a r a c t e r i z e d i n that in order to determine the magnitude of the polarization for different stimulation amplitudes, said controlling means is controlling said pulse generator (2) to deliver a low stimulation amplitude pulse below the stimulation threshold value, and calculating means (16) being adapted to determine the quantity Pol_{step} from the equation

$$Pol_{step} = \frac{U_{measlow}}{m}$$

where $U_{measlow}$ denotes the measured electrode signal obtained for the low stimulation amplitude pulse and m denotes the quotient between the low stimulation amplitude and a used voltage step and in that analyzing means are provided to determine evoked response signals by subtracting from electrode signals subsequently picked up a polarization signal of a magnitude equal to the quotient between the actual stimulation amplitude and said voltage step multiplied by the stored polarization per voltage step Pol_{step}.

4. The detector according to claim 1, c h a r a c t e r i z e d i n that said pulse generator is controlled to deliver at least one high amplitude stimulation pulse and one low amplitude stimulation pulse a plurality of times, and in that said measuring and memory means are adapted to measure the corresponding electrode signals picked up by said lead after each stimulation pulse for calculating a corresponding plurality of said quotient, said calculating means forming an average quotient value of said plurality of quotients to be used for subsequent determination of the evoked response signal.

5. The detector according to claim 2, characterized in that said pulse generator is controlled to deliver a plurality of series of stimulation pulses, each series starting with said high stimulation amplitude pulse and ending with said low stimulation amplitude pulse, and in that said calculating means is adapted to determine the magnitude of the polarization per voltage step Pol_{step} from electrode signals picked up for each series of pulses and forming an average value of the obtained plurality of polarization per voltage step Pol_{step}, said average value being stored for use as said stored polarization per voltage step Pol_{step} for subsequent determination of the evoked response signal.

6. The detector according to any of the preceding claims, characterized in that for determining the evoked response signal, said measuring and memory means are adapted to sample the electrode signal picked up by the lead with a predetermined sampling frequency during a predetermined time interval after the delivery of a stimulation pulse for calculating a mean value of these sampled values.

7. The detector according to any of the preceding claims, characterized in that said measuring and memory means are adapted to measure the electrode signal picked up by the lead before the delivery of a stimulation pulse to determine a DC level to be subtracted from the electrode signal picked up after the delivery of a stimulation pulse.

8. The detector according to claim 7, characterized in that said measuring and memory means are adapted to measure the electrode signals picked up by the lead before the delivery of each stimulation pulse of the high amplitude and the low amplitude respectively, and in that said calculation means is arranged to determine the average value of these measured signals prior to the stimulation pulses as the DC level to be subtracted from measurement signals picked up after the delivery of stimulation pulses.

9. The detector according to any of the preceding claims, characterized in that comparison means are provided for comparing said determined evoked response signal with a predetermined limit value to determine whether capture is present or not.

10. The detector according to claim 9, characterized in that said pulse generator is controlled to deliver a plurality of stimulation pulses of high stimulation amplitude and a plurality of low amplitude stimulation pulses, and in that said calculating means is adapted to form an average value of the plurality of evoked response signals resulting from the stimulation pulses of high amplitude and an average value of the plurality of evoked response signals resulting from the low amplitude stimulation pulses, said average values being supplied to said comparison means for comparison with said predetermined limit value.

Fig. 1

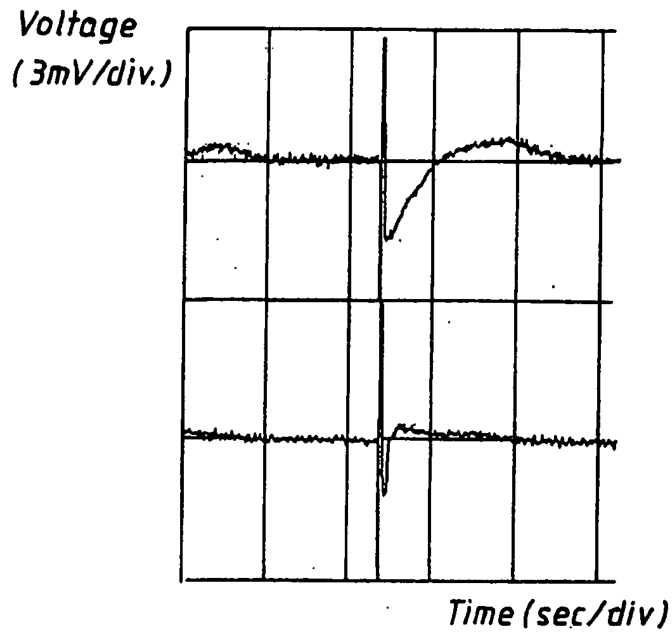

Voltage
(3mV/div.)
Time (sec/div)

Fig. 2

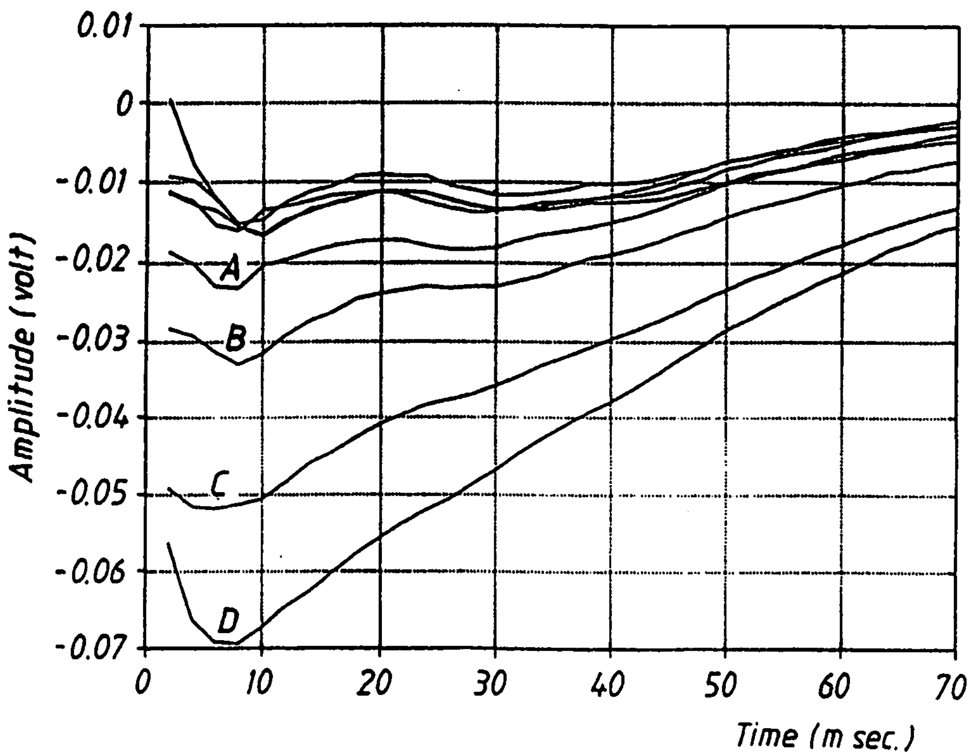

0.01
0
-0.01
-0.02
-0.03
-0.04
-0.05
-0.06
-0.07
Amplitude (volt)
A
B
C
D
0
10
20
30
40
50
60
70
Time (m sec.)

Fig. 3

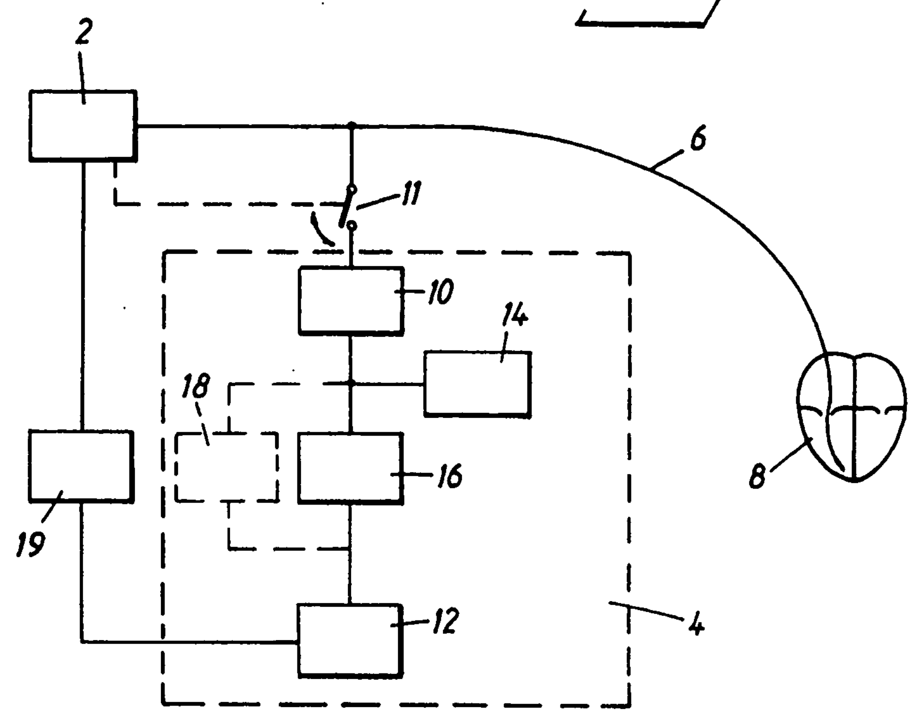
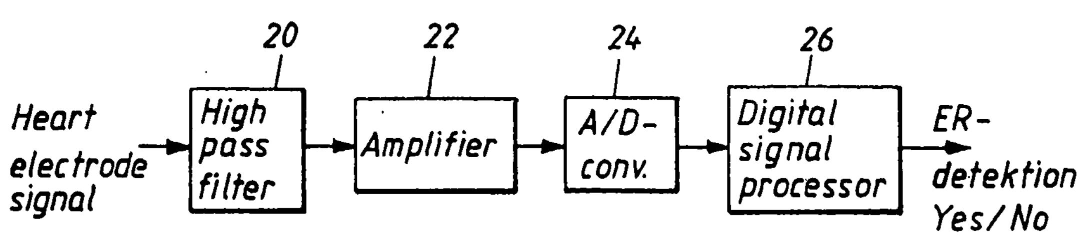

2
6
11
10
14
18
16
8
19
12
4

Fig. 4


20
22
24
26
Heart electrode signal
High pass filter
Amplifier
A/D-conv.
Digital signal processor
ER-detektion Yes/No

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/01017

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61N 1/37, A61B 5/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61N, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5741312 A (B.F.M. VONK ET AL.), 21 April 1998 (21.04.98) --	1-10
A	US 5391192 A (R.M.T. LU ET AL.), 21 February 1995 (21.02.95) --	1-10
A	US 5417718 A (J.A. KLEKS ET AL.), 23 May 1995 (23.05.95) -- --------	1-10

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 October 1999	16-10-1999
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk/AE Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT
Information on patent family members

30/08/99

International application No.
PCT/SE 99/01017

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5741312 A	21/04/98	EP 0870516 A	14/10/98
US 5391192 A	21/02/95	NONE	
US 5417718 A	23/05/95	AU 5731694 A	22/06/94
		EP 0639993 A	01/03/95
		JP 7503175 T	06/04/95
		US 5350410 A	27/09/94
		WO 9412237 A	09/06/94